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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,392	02/15/2006	Hisakazu Mihara	SAE0038	1013

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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
03/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,392	MIHARA ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,11-18 and 20-22* is/are pending in the application.

4a) Of the above claim(s) *4-6,11-14,21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 15-18 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed 12/15/08 is acknowledged. Claims 7-10 and 19 are cancelled. Claims 1-3 and 15-18 are amended. Claims 20-22 are newly added. Claims 1-6, 11-18 and newly added claims 20-22 are pending in this application. Claims 4-6, 11-14 and new claims 21-22 are withdrawn without traverse (the response filed on 5/30/08) from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

2. Claims 1-3, 15-18 and new claim 20 are under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. Applicant's arguments filed on 12/15/08 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Specification

5. The objection to the specification is withdrawn in response to Applicant's amendment to the specification.

Claim Rejections/Objections Withdrawn

6. The rejection of claims 1-3, and 7-10 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in response to Applicant's amendment to claims 1-3 and cancellation of claims 7-10.

The rejection of claims 7-10 and 19 under 35 U.S.C. 101 & 112-1st paragraph is moot because the claims are canceled.

The rejection of claims 1-3, 7-10, 16 and 19 under 35 U.S.C. 112, first paragraph, because the specification, were it enabling for the artificial peptides (SEQ ID NOs: 2-4), does not enable the invention commensurate in scope with the claims is withdrawn in response to Applicant's amendment to the claims by reciting specific SEQ ID NOs: and cancellation of claims 7-10 and 19.

The rejection of claims 1-3 and 7-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to Applicant's amendment to the claims by reciting specific SEQ ID NOs: and cancellation of claims 7-10.

The rejection of claims 1 and 7 under 35 U.S.C. 102 (b) as being anticipated by Tjernberg et al (J. Biol. Chem. 1999. 274:12619-12625 as in IDS) is withdrawn in response to Applicant's amendment to the claim by reciting specific SEQ ID NO: and cancellation of claim 7.

Claim Rejections/Objections Maintained

In view of the amendment filed on 12/15/08, the following rejections are maintained.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 15-18 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The rejection is maintained for the reasons made of record.

On p. 14 of the response, Applicant argues that the amplification of the amyloid fibrils is performed ex vivo and thus does not result in a more serious pathological condition. Applicant argues that claimed reagents could be used to amplify and measure a minimum amount of Abeta in plasma. Applicant further cites Mehta et al. (Neuroscience. 2001. 304: 102-106) and Schupf et al. (PNAS 2008, 105:14052-14057) in support of the argument that the causal relationship between Abeta in plasma and Alzheimer's disease. Applicant's arguments have been fully considered but they are not persuasive.

In response, it is noted that the reference of Schupf et al. is a post-filing date reference. The invention must be enabled or have a specific and substantial utility at the time of filing and, therefore, the enablement cannot be supported by later obtained experimental results. In *In re Rasmusson v. SmithKline Beecham Corp.* 75 USPQ2D 1297, p1301. "Enablement, or utility, is determined as of the application filing date." *In re Brana*, 51 F.3d 1560, 1567 n.19, 34 USPQ2d 1436, 1441 n.19(Fed. Cir. 1995). The

post-filing publication does not mirror the state of the art at the time the invention was filed and the application has presented no evidence to show that this reference represents the state of the art as of the effective filing date of the instant application.

Post-filing date evidence can be relied on to support utility only where it shows the state of the art as of the application's effective filing date. See *In re Hogan*, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977). See also *In re Glass*, 492 F.2d 1228, 1232, 181 USPQ 31, 34 (CCPA 1974): "[A]pplication sufficiency under § 112, first paragraph, must be judged as of its filing date. It is an applicant's obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file." Although both *Hogan* and *Glass* concerned enablement, the same standard applies to utility under § 101. See *In re Brana*, 51 F.3d 1560, 1567 n.19, 34 USPQ2d 1436, 1441 n.19 (Fed. Cir. 1995) ("Enablement, or utility, is determined as of the application filing date.").

Nevertheless, the instant specification fails to show any utility for the claimed peptides. As previously made of record, the instant specification fails to demonstrate that the claimed reagent has a specific and substantial asserted or well-established utility. The claimed artificial peptides may be used to test whether the biochemical property of the peptides in forming aggregation of Aβ10-35 in vitro or study the interaction between the claimed peptide and Aβ10-35 in vitro. But these studies are not defined as a "real world" utility. The instant specification fails to teach the relevance

between the finding of enhanced Aβ10-35 aggregation by the claimed peptides and diagnosis of AD. The specification only shows that artificial peptides 10-3F, 10-4F and 10-3L (SEQ ID NOs: 2-4) can form amylod fibris and also increase fluorescent intensity in the presence of the nucleus (Aβ10-35) in a test tube.

Although amyloid fibris formation can be found in the brain of AD patients, the specification does not teach what the relevance between the enhanced Aβ10-35 aggregation by the claimed peptides in vitro and the diagnosis of AD or any particular disease is. The specification also fails to teach how to use such claimed peptides in diagnosis of Alzheimer's disease (AD) and fails to teach whether the claimed peptide can really be used to diagnose a person and determine whether the person is suffering from AD or other disease. Thus, the claimed reagent has no specific and substantial or well-established utility.

Note that

A< "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. … On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
(B) A method of treating an *unspecified* disease or condition;
(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
(D) A method of making a material that itself has no specific, substantial, and credible utility; and
(E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility. See MPEP 2107.01.

In this case, the enhancement of Aβ10-35 aggregation by the claimed peptides shown in the specification is only limited to a basic research to study the biochemical

properties of the claimed peptides. The instant specification fails to demonstrate that such claimed peptides indeed can be used for diagnosing AD.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 15-18 and 20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The rejection is maintained for the reasons made of record. Since the instant specification does not disclose a substantial "real world" use for the claimed reagent as set froth above, a skilled artisan would not how to use the claimed invention.

Conclusion

8. NO CLAIM IS ALLOWED.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
March 05, 2009

/Christine J Saoud/
Primary Examiner, Art Unit 1647